THE USE OF CELL DEMODULATED ELECTRONIC TARGETED ANESTHESIA TO CONTROL DENTAL OPERATIVE PAIN IN PEDIATRIC PATIENTS

by

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Submitted to the Graduate Faculty of the School of Dentistry in partial fulfillment of the requirements for the degree of Master of Science in Dentistry, Indiana University School of Dentistry, 1999.

Thesis accepted by the faculty of the Department of Pediatric Dentistry, Indiana University School of Dentistry, in partial fulfillment of the requirements for the degree of Master of Science in Dentistry.

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ACKNOWLEDGMENTS

I wish to thank the faculty and staff of the Department of Pediatric Dentistry at Indiana University School of Dentistry and James Whitcomb Riley Hospital for Children for making my graduate education rewarding and enjoyable.

Thanks are extended to Dr. Douglas Barton, Dr. David Avery, Dr. Brian Sanders, Dr. James Weddell, and Dr. Angie Tomlin for participating on my graduate committee.

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INTRODUCTION

Fear and the anticipation of pain from an injection of local anesthetic remains one of the foremost obstacles to providing dental care. This is especially true for the pediatric population, who often have a very real fear of needles from their experiences with childhood immunizations.

One form of pain control is an electronic dental anesthesia device that introduces a low frequency blocking signal that penetrates tissue at low power and is targeted to a treatment site. This technique of Cell Demodulated Electronic Targeted Anesthesia offers the possibility of a noninvasive analgesic technique without the associated pain and lingering paresthesia of a local anesthetic injection.

Many studies using different types of electronic dental anesthesia have been completed on adults as well as limited studies on pediatric patients. The purpose of this investigation was to provide data comparing the anesthetic effectiveness between Cell Demodulated Electronic Targeting Anesthesia and traditional local anesthesia during treatment of teeth requiring full coverage stainless steel crowns with or without pulp therapy in a pediatric population.

REVIEW OF LITERATURE

The concept of using electricity for the reduction of acute pain is not new. The earliest records of this come from the classical Greek civilization, where it was reported in 46 A.D. that electrical fish were used to numb painful areas of the body.[1] While walking on the beach, Anthgero's arthritic pains were cured when he accidentally came into contact with a live torpedo fish.[1] This fish, the Torpedo Marmorata, emits 40 to 50 volts with a frequency of 100 to 200 Hz and an impulse train of 100 to several thousand.[2] In the middle ages, Redi, Perault, Ricker, and Lorenzini also described the numbing effects of the torpedo fish.[2] In the 16th century, Dawud Al Antki claimed that the torpedo fish could relieve chronic headache, unilateral headache, and vertigo even in desperate cases.[3] In the 17th century, Otto Von Guerick developed the electrostatic sulfur sphere,[4] which in the 18th century was incorporated into an electrostatic generator by F. Haukshbee.[5] In 1745, Leyden jar condensers were invented by Georg Von Kleist and Pieter Van Musschenbrock.[5] When these devices, which were capable of storing electrical charges, were combined with an electrostatic generator, evangelist-preacher Reverend John Wesley used them to relieve the pains associated with gout, headaches, and sciatica.[4,5] In the mid 1700s, Walsh[6] and Cavendish[7] described the use of electrical machines that produced numbing paresthesia.

In 1753, a book on medical electricity, the *Subtil Medium Proved,* was published by Richard Lovett. He described dozens of cures for many illnesses using electricity.[8] Benjamin Franklin also used electricity as a therapeutic modality. In one recorded case, he used an

electrostatic generator to treat a woman with seizures.[9] In 1772, John Birch described using electrotherapy to cure a woman of chronic constipation.[10]

In the late 1700s, the oriental practice of acupuncture was introduced to the western world.[5] It was not until 1821 that acupuncture gained notoriety from Churchill's work.[11] Sarlandiere[12] in 1825 described combining electricity and acupuncture, "electropuncture," to control pain. This type of therapy became an accepted method, particularly in France.[13] E. Hermel in 1844 treated sciatic and lumbosacral neuralgia by galvanic "electropuncture" using two needles for electrodes.[14]

According to Malamed,[5] the first reported use of electricity in dentistry was in 1770 when a woman's toothache was permanently stopped when the tooth was shocked with electricity. In 1858, Francis[15] extracted 164 teeth while having an electrode on the tooth and another held in the patient's hand. Reportedly, most patients felt no pain. Also in 1858, W.G. Oliver reported 98-percent success using a generator for extractions.[8] In that same year, he described using electrotherapy to control pain while surgically removing a leg ulcer. Oliver also recommended electrical analgesia during childbirth. A wire would be placed around each ankle, another at the waist, and one around the neck.[2]

In 1859, electroanalgesia was used for trigeminal neuralgia, extractions, toothache, and jaw-ache relief by Garrat.[16] He stated that the electrodes should be placed on the edge of the painful site for 3 to 5 minutes with a just-bearable current.

Due to the controversy of electroanalgesia, in 1859 the College of Dentists of London appointed a commission to examine the effect of electrical anesthesia in dentistry.[17] It was concluded that electricity was not an anesthetic agent; it augmented pain -- sometimes modifying the sensation produced. When favorable results were produced, they were due to a

diversion and not a true insensibility.[17] However, after a member of the commission had an extraction done using electrical anesthesia, he changed his opinion.[18]

In 1861 Tripier[19] described how attaching extraction forceps to the negative lead of a medical induction coil, while having the patient hold the positive electrode in hand, would result in infinitely less painful extractions. In 1890, pulsed and bipolar electricity from a magneto or induction coil was recommended for the treatment of toothache.[5]

Throughout the early 1900s the application of electroanalgesia diminished in dentistry as in medicine, because of variable and non-reproducible results,[2] and possibly because of the development of the local chemical anesthetic Procaine in 1904,[20] which, along with other local anesthetics, provides pain-controlling effects by causing a depression of excitation in nerve endings, or an inhibition of the conduction process of peripheral nerves.[21] Despite this decline in popularity, electrical anesthesia devices continued to be mentioned in the literature. In 1918, Ernest Sturridge[22] described the use of low-voltage direct current to tissues to produce anesthesia.

Suzuki[23] in 1952 reported passing 4 to 10 mA through the bur of a dental handpiece to reduce pain during cavity preparation. Unfortunately, to have an effect, the bur had to be in contact with the tooth. Later in 1970, Brooks et al.[24] described generating an electrical current by wrapping a fine wire around a bur and running the bur in a magnetic field. They reported 66-percent success during operative procedures. The use of an electrified Russian handpiece, the *Sin Dolar,* was described by Ehrlich[25] in 1973. The negative electrode from the device was attached to the patient's ear, and the positive electrode was attached to the drill. The handpiece was found to be unpredictable, providing mixed results. Bradley et al.[26] in

1974, described the use of a handpiece containing an electrical generator in the head, the Densensor. This handpiece was able to deliver a current of 6 volts to the tooth. Reportedly, patients had less discomfort than with ordinary handpieces. Laster and Pressman[27] in 1975 described using a Soviet direct-drive electrified handpiece, the *ELOZ-1*, that was converted to an air turbine handpiece. They reported poor results. Savage,[28] a number of years later, reported similar difficulties with a similar Soviet electroanalgesic device.

Melzack and Wall's[29] gate-control theory created substantial renewed interest in electroanalgesia. In 1967 Wall and Sweet[30] showed that by stimulating peripheral nerves with implanted electrodes, pain impulses could be inhibited. They were able to alleviate severe and chronic pain of cutaneous origin with relief lasting as long as 30 minutes after a two-minute administration of stimulation.

Shealy et al.[31] showed that by applying an electrical current to electrodes that were implanted in the dorsal column of the spinal cord, pain signals could be prevented from ascending to higher perception areas. In an attempt to show how these stimulations would feel, Shealy attached electrodes to the skin and applied a current. This marked the introduction of transcutaneous electrical nerve stimulation (TENS).[10, 31]

From its introduction until the late 1970s, TENS' applications have been mainly in the field of medicine.[32] TENS has found its greatest use in physical therapy for rehabilitation and chronic pain control.[33] Today, TENS refers to devices that apply a low-voltage electric impulse directed to chronic pain areas via surface electrodes.[34]

Although the exact mechanism of action of electroanalgesia is not known, multiple theories have been formulated over the past 20 years to explain how electricity is able to block the transmission of pain. One such concept is the gate-control theory, which states that pain is

transmitted to the brain by two different types of nerve fibers -- the A-delta fibers (small-diameter, myelinated-associated, with fast, well-defined pain) and the C fibers (unmyelinated-associated, with slow, diffuse, long-duration pain).[29,35] Tooth pulp is richly innervated and contains both A-delta and C nerve fibers.[36] These small diameter fibers have a rate of transmission that is slower than the large diameter, myelinated A-beta fibers that are responsible for the sensations of touch and pressure.[29,35]

It is theorized that synaptic gates in the dorsal horn of the spinal cord and trigeminal spinal nucleus allow transmission of the A-delta and C fibers to higher levels of the brain.[35] When the large A-beta fibers are activated by touch, pressure, or electrical stimulation, resulting impulses travel to the spinal ganglion. These impulses arrive sooner than A-delta and C fiber pain impulses. Because only a certain number of impulses can be accommodated at the ganglion at any one time, the gate is closed, hence suppressing A-delta and C fiber pain impulse transmission to higher levels of the brain.[29,35] At the present time, details of the gate-control mechanisms are controversial.[37]

Another theory helping to explain the mechanism of electrical analgesia was postulated by Hughes et al.[38] in 1975. In response to noxious stimuli, endogenous opiate peptides (endorphins and encephalons) and neurochemicals such as 5-hydroxytryptamine become liberated within the central nervous system.[38] These substances attach to opiate receptors[39] and cause activation of descending pathways leading to the suppression of nociceptive transmissions.[40] Adams[41] found that some of the analgesic effects of electrical stimulation could be reversed with injections of naloxone (a narcotic antagonist). A more recent study by Abram et al.[42] revealed that factors other than endorphin release also help to block pain.

A third theory by Wolf[43] and Mannheimer and Lampe[44] describe that increased blood levels of serotonin or L-tryptophan result in increased tolerance to pain. Several other less popular theories have been offered as explanations for the effects of electrical analgesia. Among these are the importance of dopamine, norepinephrine, and electrocoagulation.[45] The exact mechanism in which electrical stimulation influences pain perception is not yet understood and may be a combination of one or more theories.[35] Woolf and Thompson[46] suggest that the activation of segmental inhibitory circuits in the spinal cord supplemented by descending inhibitory pathways explain electrical analgesia's mechanism of action.

There have been numerous reports of TENS and other electroanalgesic devices being used in dentistry. These devices have been referred to by many names including TENS, MANS (muscular and neurologic stimulation), dental electroanesthesia, and electrostimulation. The use of the more general term, electronic dental anesthesia (EDA), has been encouraged.[46,47] Throughout the literature, the two terms, EDA and TENS, are used interchangeably.[35]

The frequency of electrical signals vary with different EDA devices. Typically EDA devices produce one of the following: a balanced, symmetrical, biphasic, exponentially decaying wave form (H-wave), or a balanced, asymmetric square wave form, or a semi-square wave form balanced by a square wave of opposite polarity.[8] Low frequencies have been advocated in the treatment of chronic pain, while higher frequencies are thought to be more useful in providing acute pain analgesia and anesthesia.[48]

There are many references in the literature describing the use of EDA for the treatment of myofascial pain dysfunction (MPD) syndrome and temporomandibular dysfunction (TMD). Meizels,[49] with the use of TENS, increased the range of motion and reduced pain in TMD

patients. Quarnstrom,[50] in a study combining nitrous oxide analgesia and EDA, treated TMD with a 2-Hz signal for 15 minutes and then a 120-Hz signal for the next 15 minutes. An 80-percent improvement in range of motion was noted, and pain was noticeably less in all patients. Markovich[51] in 1977 described using a TENS device to reduce muscle spasms associated with MPD. Denholtz[52] and Terezhalmy et al.[53] also used TENS to treat TMD and MPD patients. Block and Laskin[54] conducted a controlled study using an active TENS device and a placebo TENS device to treat MPD patients. It was concluded that TENS treatments were somewhat effective. Gold et al.[55] in another controlled study using TENS found that it had the same 60- to 70-percent initial success rate that a placebo device had. Bishop,[56] however, reported a 100-percent success rate in treating MPD with a high frequency neural modulator as compared with zero-percent success with a placebo device. Horiuchi[57] suggested that low frequency stimulation may provide more reliable relief for chronic myofascial pain.

Numerous studies have been conducted to evaluate the effect of EDA devices on the perception of pain in human teeth. Rooney and Tronstad[58] examined what effect TENS had on the pain perception threshold (PPT) and the pain tolerance level (PTL) of teeth that were stimulated with an electric pulp tester. No significant differences were found between groups using an active TENS device and those using a placebo device. Andersson,[59] however, reported that peripheral electrical stimulation of 2 Hz caused a 200- to 300-percent increase in tooth pain perception threshold. In another study, Bakke[60] reported a 17-percent increase in tooth pain perception threshold when a current of 100 Hz was applied. Mumford[61] in 1976 noted a significant increase in PPT when using TENS. An insignificant increase in PTL was also noted in this study when using TENS. Hansen and Lambjerg[62] in a later study did not report a significant increase in PPT when TENS was used. Cameron et al.[63] also found no

significant difference in pain threshold when either an active EDA device was used or a placebo device was used.

In 1989 Abdulhameed et al.[64] conducted a double-blind study using different frequency peripheral electrical stimulation devices to evaluate tooth pain perception threshold in 30 children. Electric pulp testing and rubber dam application served as stimuli. It was found that regardless of the frequency used, tooth pain threshold was increased 33-percent compared with a 13-percent increase from the use of a placebo device.

Ihalainen et al.[65] and Pertovaara[66] have also found electrical stimulation to increase tooth pain threshold. In a 1991 study, Gershman and Giebartowski[67] compared the effects of square wave EDA and H-wave EDA on the PPT and the PTL of pulp-tested teeth. Both wave forms significantly increased PPT and PTL compared with placebo devices. It was noted that H-wave EDA was more effective than square wave EDA. Abdulhameed et al.[64] reasoned that tooth pain threshold increases were due to variations in EDA intensity rather than frequency.

EDA has been used with good success to manage pain associated with scaling and root planing procedures. Hochman[68] reported an 83-percent success rate when TENS was used for scaling and prophylactic procedures. Bishop[56] in a 1986 study achieved 100-percent success rates when using high-frequency neural modulation to control pain associated with scaling and root planing procedures. A placebo device was zero-percent successful for these procedures. These results were duplicated in a 1987 study by Clark et al.[69] also using a high frequency neural modulation device. In a 1994 single-blind study, Jacobs and van Steenberghe[70] examined pain-controlling effects of an EDA device attached to a sonic scaler during periodontal treatment. It was concluded that the EDA device was insufficient to eliminate the sensation of pain associated with sonic scaling.

Many studies have been conducted that evaluate the effects of EDA during dental operative procedures. Hansson and Ekblom[71] in 1984 described the use of 2-Hz and 10-Hz TENS devices that used extraoral electrodes to control dental operative pain. It was concluded that insufficient amounts of analgesia were produced by the devices and that the use of intraoral electrodes would be more efficacious. In a double-blind study using intraoral EDA for simple operative procedures, Bishop[56] reported a 93-percent success rate for active devices as compared to zero-percent success with placebo devices. Curcio et al.[32] using TENS with intraoral electrodes, found that the active devices produced an 84.6-percent success rate for simple operative procedures as compared with a 61.9-percent success rate for a placebo device. Clark et al.[69] using a high-frequency neural modulator to control pain, had a 92.9-percent success rate for restorative procedures. A placebo effect was noted in 42.9-percent of procedures. In a 1989 study by Malamed et al.[72] the pain controlling effects of EDA on Class I, II, III, IV, and V restorations were examined. The overall success rates were found to be 85.8-percent for shallow restorations, 85.5-percent for moderate restorations, and 59.5-percent for deep restorations. It was also noted that anterior teeth had higher success rates than posterior teeth.[72, 73] In a double-blind study, Hochman,[68] using a TENS device with extraoral and intraoral electrodes, noted a 76-percent success rate for restorative procedures and a 55-percent success rate for crown preparation procedures. Hochman[68] also concluded that EDA success rates were influenced by the degrees of skepticism, pain sensitivity, and relaxation of the patient.

Mellor[74] in a 1993 study compared local anesthesia with EDA for controlling pain associated with simple operative procedures. Sixty percent of patients preferred EDA; 28-

percent had no preference, and 12-percent preferred local anesthetic. In a double-blind study using active and placebo EDA devices, Matranga et al.[75] found that during simple operative procedures, a 98-percent success rate was obtained. The success rate of the placebo device was 52-percent. The high placebo and EDA success rates could have been because in many simple operative procedures, anesthesia is not always necessary. It has been demonstrated that restorative treatment without anesthesia has high success and acceptance rates among patients. Taub et al.[76] reported that 90.2-percent of patients who preferred not to use local anesthetic experienced mild or no pain.

Harvey et al.[77] in a double-blind study involving class I alloy restorations and EDA, noted a statistically significant decrease in pain perception when an active EDA device was used compared with a placebo device. In a similar double-blind study, Schanzer and Black[78] examined the effects of an EDA device on pain associated with class I and II operative procedures. It was concluded that the results of the study did not overwhelmingly support EDA for the control of dental operative pain. A significant placebo effect was also noted.

Studies have been performed using EDA in combination with nitrous oxide. Quarnstrom[50] in 1988 examined the effects of H-wave and square wave TENS devices with nitrous oxide in concentrations of 35- to 45-percent to control pain associated with operative and crown and bridge procedures. A variety of intraoral electrodes were evaluated when both EDA and nitrous oxide were combined. Success rates of 88-percent were achieved when EDA was used in conjunction with nitrous oxide. EDA used alone yielded success rates of 68-percent, while nitrous oxide used alone was 42-percent successful. No differences in effectiveness were noted among the various TENS devices.[50] In a 1993 study, Quarnstrom[79] compared the effectiveness of nitrous oxide and H-wave EDA with nitrous oxide and square

wave EDA. There was no difference in effectiveness between the two wave forms in controlling pain associated with simple operative and crown and bridge procedures. In another study, Quarnstrom and Milgrom[80] reported the combined use of EDA and nitrous oxide to be 82-percent successful, while TENS alone was 53-percent successful. It was also noted that regardless of technique used, fearful patients experienced greater pain than relaxed patients. Donaldson et al.[73] also conducted a study combining nitrous oxide with EDA for dental operative procedures. It was found that EDA alone and nitrous oxide alone yielded success rates of 33-percent and 36-percent respectively. However, when used in combination, success rates of 85-percent were achieved.

EDA has also been used to manage pain associated with endodontic and extraction procedures. Bishop[56] reported that endodontic procedures were zero-percent successful, and extraction procedures were 67-percent successful with the use of high frequency neural modulation. Clark et al.[69] also reported that EDA pain control was zero-percent successful for endodontics, and 66.7-percent successful for the extraction of erupted teeth. Strassburg,[81] using TENS for tooth extractions and minor surgical procedures, found that pain control was adequate in 98-percent of patients. Hansson and Ekblom,[71] however, found TENS to be inadequate for these procedures.

In 1985 Gu et al.[82] stated that electropuncture (EDA combined with acupuncture) was 80.12-percent successful for tooth extractions. Maxillary anterior teeth had the highest success rates. Gu et al.[82] found electropuncture to be ineffective for impacted teeth and acutely inflamed teeth.

The use of TENS has been reported to be effective in controlling post-operative pain associated with the extraction of mandibular 3rd molars.[83] TENS has also been used for post-

operative pain management after mandibular subperiosteal implant surgery.[84] Post-operative TENS treatment allowed patients to require less pain medication and have decreased swelling with an increased healing rate.[84]

A number of studies using EDA for dental procedures have been performed on children. Many of these studies have used a visual analog scale (VAS) to evaluate comfort levels of patients during treatment. The VAS is ideally suited for use by children in assessing pain, because VAS does not require children to understand numbers or to understand certain pain words. A VAS is a form of cross-modality matching in which the length of a line or a degree of unhappiness displayed on faces is adjusted to match the strength of a certain perception. Children from 3 to l6 years of age have used the VAS to rate the intensity and unpleasantness of acute pain, recurrent pain episodes, post-surgical pain, phantom limb pain, and chronic pain.[85] Generally, children over 5 years of age are able to use VAS in a reliable and valid manner to describe their perceptions, independent of their health status or sex.[85] Wong and Baker found that the faces pain-rating scale was more reliable and valid than the traditional VAS, which was composed of a line with 10 numerical points assigned to it. They also found that children preferred using the faces pain-rating scale to the traditional VAS.[85]

TeDuits et al.[35] compared local anesthesia to EDA in 6- to 12-year-old children receiving two posterior teeth restorations in the same appointment. No overall significant difference in pain perception was noted between local anesthesia and EDA. Seventy-eight percent of the patients preferred EDA compared with 22 percent, who preferred local anesthesia.[35]

Modaresi et al.[86] in a double-blind study using EDA to control dental operative pain in children, found that almost as many restorations were able to be completed in the placebo

group as in the active EDA group. In another double-blind study, Harvey and Elliott[87] evaluated a TENS device for controlling discomfort associated with class I cavity preparations in pediatric patients. A visual analog scale was used to assess patient discomfort. The active TENS device was found to be 100-percent successful, while the placebo device was zero-percent successful in controlling pain.

Croll and Simonsen,[88] in a study involving 45 children aged 3 to13 years, performed procedures including extraction of primary teeth with resorbing roots or class II restorations. Thirty-seven of these children were successfully treated with EDA alone. They suggested that EDA should be used in children as an adjunctive option, and that EDA could be used alone or in combination with nitrous oxide, auditory diversion with music, or to complement traditional local anesthetic needle injection procedures.[88]

Jedrychowski and Duperon[89] conducted a study to determine the efficacy and acceptance of EDA in pediatric patients. Procedures performed involved stainless steel crowns, anterior composite crowns, and amalgam and composite restorations. No patients in the study reported severe discomfort, and only 2 out of 40 reported moderate discomfort requiring injection of local anesthetic to complete treatment. Even after local anesthetic administration, the two children still reported discomfort. All patients who had experienced local anesthesia in the past preferred EDA.[89]

In a 1995 study, Segura et al.[90] evaluated the effectiveness of an extraoral EDA device when used to treat 15 children aged 7 to12 years who had experienced dental treatment with local anesthetic in the past. Procedures were performed on primary molars and included 14 Class II restorations and one stainless steel crown. Reportedly, most children experienced minimal pain.

In another 1995 study, Sasa and Donly[91] compared local anesthetic with an extraoral EDA device during invasive operative treatment on 6- to 14-year-old children. Procedures included Class II restorations and stainless steel crowns with and without pulpotomies. It was concluded that the EDA device was not effective for invasive restorative procedures in the mandibular arch.

Larmour et al.[92] in a 1993 study placed two comparable restorations in permanent teeth of children at different appointments with either EDA or local anesthesia. It was concluded that patients experienced less pain with local anesthesia and preferred it to EDA for simple restorative procedures.

In a similar 1998 study, Cho et al.[93] compared local anesthetic with EDA during Class I and II restorations on primary and secondary anterior molars on 6- to 12-year-old children by using a visual analog scale. It was found that EDA was less effective than local anesthetic for cavity preparation. Also, reported pain scores for EDA were higher in permanent teeth for deeper cavities. Quarnstrom,[50] in a study using EDA and nitrous oxide for restorative procedures, found that patients under 13 years of age had success rates of 97-percent, whereas 14- to 18-year-olds had only 70-percent success rates.

Recently a new type of EDA has been introduced, Cell Demodulated Electronic Targeted Anesthesia (CEDETA).[94] Its manufacturer, Cedeta Dental International, Inc., proposes that its EDA device targets a specific electronic wave form directly to the nerve bundle at the root of the tooth by introducing two slightly different-high frequency signals of very low current through disposable contact pads placed on the back of each hand. The two high-frequency signals easily travel through the body (unlike low-frequency signals) and are drawn to a disposable receptor (exit electrode), which is placed on the gingiva at the treatment

site and acts as an antenna. The two slightly different high-frequency signals mix at the receptor and leave a low-frequency blocking signal equal to their sum. This resulting blocking signal encompasses the volume of tissue around the receptor.[94,95] According to the CEDETA Mk2 Operating Manual:[94]

> The Cedeta technology is physiologically similar to that of local chemical anesthesia. The Cedeta signal reduces the sodium/potassium ion exchange. As a result, the charge polarity of the nerve cell wall is prevented from changing and is therefore unable to carry pain impulses. The Cedeta signal only affects non-myelinated pain ("C") fibers. The blocking signal does not affect sensory fibers which are surrounded by a myelinated sheath that acts like an insulator. Therefore, the Cedeta blocking signal does not affect the transmission of touch, mild temperature changes or location awareness (proprioception). Cedeta does block pain from the extreme temperature changes.
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> In addition to Cedeta's direct effect on blocking nerve impulse conduction, Cedeta causes stimulation of natural endorphins and serotonin. Therefore, using Cedeta has a secondary effect in producing localized analgesia at the treatment site, which develops in proportion to the length of time of the application. This secondary effect accounts for raising of the pain threshold and post-treatment residual analgesia.

The purpose of this study is to compare the effectiveness of Cell Demodulated Targeted Anesthesia to local anesthetic during treatment of teeth requiring full coverage stainless steel crowns with or without pulp therapy in a pediatric population. It is hypothesized that the CEDETA device will provide pain-controlling effects that are comparable to those of local anesthetic.

METHODS AND MATERIALS

Patients between the ages of 6 and 12 years were recruited for the study from the Indiana University Department of Oral Facial Development and from The Dental Center in South Bend, Indiana. All of the children who were eligible to participate and their parents received an explanation of the procedure and had an opportunity to ask questions concerning the study, local chemical anesthesia, and the Cell Demodulated Electronic Targeted Anesthesia (CEDETA) unit. Those who agreed to participate in the study were asked to sign an Informed Consent Form (Appendix A). Patients with a medical history that included: epilepsy, cochlear implant, heart disease, cardiac demand pacemakers, or other cerebrovascular disorders, and patients unable to understand directions were excluded from the study. Also, patients taking the medications Elavil or Prozac were excluded from the study. Dental phobics and patients who were unusually fearful or uncooperative due to past dental experiences were also excluded. All participating patients had a carious maxillary primary molar in need of a stainless steel crown restoration. No anterior teeth were treated in this study. Also, teeth with frank periodontal problems were excluded from this study. Nitrous oxide analgesia was not used in this study.

The study involved 32 patients who received Cell Demodulated Electronic Targeted Anesthesia as their method of pain control at an operative appointment, and 31 patients who received conventional local anesthetic as their method of pain control at an operative appointment. Before treatment, patients were randomly selected to receive Cell Demodulated Electronic Targeted Anesthesia (CEDETA) or local chemical anesthesia.

After the patient had been seated for the appointment and before any procedure was done, the patient was shown a 6-point visual analog scale (VAS) (Appendix B) and asked to assess his or her level of apprehension towards dental treatment by selecting the appropriate facial type. This provided a pre-operative assessment or baseline level of the patient's general anxiety towards dental treatment.

At the local anesthetic appointment and after the pre-operative assessment had been completed, it was explained to patients that they would receive some medicine that would make their tooth go to sleep. The patient would be reclined to a supine position and the mucosa at the site of the injection would be thoroughly dried with a 2 x 2 gauze. Twenty-percent benzocaine gel (Topex, Sultan Dental Products, Ltd., Englewood, NJ) on a cotton swab applicator would be gently applied. After 30 seconds had elapsed, 1.8 cc of 2.0-percent Lidocaine with 1:100,000 Epinephrine delivered with a 30-gauge needle would be administered by the guidelines stated in Chapter 13 of McDonald and Avery, *Dentistry for the Child and Adolescent.*[96]

After the injection had been completed and the needle properly recapped, the patient would immediately be asked to assess his or her level of discomfort by selecting the appropriate facial type on the visual analog scale. After 10 minutes had elapsed, the carious tooth would be isolated with a rubber dam clamp and a rubber dam. The highspeed handpiece would then be activated and held just above the tooth that was to be treated. Again, the patient would be asked to assess his or her level of discomfort during the procedure by selecting the appropriate facial type on the visual analog scale. At 30 minutes post-injection, after completion of tooth preparation, and pulp therapy if necessary, the patient would be asked to assess his or her level of discomfort by selecting the appropriate facial type on the visual analog scale. If needed, a base would be placed; the tooth would be restored with a stainless steel crown, and the rubber dam

would be removed. The total time of the procedure would take no longer than 30 minutes. Finally, before patients were dismissed, they would be asked to rate their overall dental experience by selecting the appropriate facial type. Responses were recorded on the Local Anesthetic Appointment patient forms (Appendix C).

At the CEDETA appointment, after the pre-operative assessment had been completed, the patient would be familiarized with the CEDETA device and how it was controlled and then be reclined to a supine position. The skin on the back of both hands would be wiped clean with an alcohol gauze. This was done to remove any oil that could compromise the uniform conduction of the high-frequency signal or interfere with the proper adhesion of the contact pads. A contact pad would then be placed firmly on the back of each hand. The disposable intraoral electrode was available in one size only. Before placement, the intraoral receptor would be trimmed for proper fit with scissors, so that it would cover as much of the attached gingiva as possible without touching the tooth and without being too close to the gingival margin. At the treatment site, the palatal gingiva would be dried completely using gauze. Once the receptor was in position, it would be pressed down with a single firm action, so that the hydrogel adhesive on the receptor would fill in the uneven surface of the gingiva. Once the intraoral electrode was placed, the amplitude of the current was gradually increased until a tingling sensation on the gum was reported by the patient. After a brief period of time, the tingling sensation would decline and disappear. The patient, who controlled the amplitude, would then increase the amplitude to restore the tingling sensation, so that it was strong without causing discomfort. This was repeated until there was a strong, sustained, yet comfortable tingling sensation. At this time, they would be asked to evaluate their level of discomfort by selecting the most appropriate facial type on the visual analog scale (Appendix B). The carious tooth would then be isolated with a rubber dam clamp and a rubber

dam. The highspeed handpiece would then be activated and held just above the tooth that was to be treated. At that time, the patient would be asked to assess his or her level of discomfort by selecting the appropriate facial type on the VAS. Preparation of the tooth would be completed, including pulp therapy if necessary, and the patient would be asked to assess his or her level of discomfort by selecting the appropriate facial type. If needed, a base would be placed, the tooth would be restored with a stainless steel crown, and the rubber dam would be removed. The total time of the procedure would take no longer than 30 minutes. During the procedure, the patient would be allowed to increase the amplitude of the current to maintain comfort. Before being dismissed, the patient would be asked to rate his or her overall dental experience by selecting the appropriate facial type. Responses were recorded on the CEDETA Appointment patient form (Appendix D).

If either the CEDETA device or a single carpule of local anesthetic did not produce adequate anesthesia for completion of the dental preparation and required any additional adjunctive anesthetic agents, a score of 5 would be automatically assigned to the preparation phase of the evaluation.

At both the CEDETA and local anesthetic appointments, the operator would assess his perception of the patient's level of discomfort each time the patient was asked to use the VAS. Responses were recorded on the Operator Assessment form (Appendix E).

RESULTS

A total of 63 procedures were performed on 55 children aged 6 years, 0 months, to 10 years, 6 months in this study (Table 1). Eight of these children had stainless steel crown restorations placed on primary maxillary posterior teeth at two separate visits with random use of CEDETA or local anesthetic. [Of these eight patients, five were males and three, females (Table II).]

Thirty-two stainless steel crown restorations were placed using the CEDETA device, while 31 used local anesthetic. Thirty-one percent of the procedures were with males using the CEDETA device, 28-percent with males using local anesthetic, 19-percent with females using the CEDETA device, and 20-percent with females using local anesthetic (Table III).

Table IV shows the distribution of teeth treated in this study. Ten procedures involved upper right second primary molars; 16 involved upper right first primary molars; 23 involved upper left first primary molars, and 14 involved upper left second primary molars. The distribution and type of pulp therapy performed on teeth in the study are shown in Table V.

At five different times during each operative procedure, the operator and the patient graded the patient's perception of pain as a continuous response variable on a scale of 0 to 5, with 5 as the worst pain. Tables VI-X compare the operator's ratings to tse of the patients'. Agreement between the patients' and the operator's ratings was measured using Kappa and Weighted Kappa statistics. Table XI shows the extent of agreement between the patients' and operator's ratings. Patient and operator ratings for each of the five questions were analyzed separately. The CEDETA and local anesthetic groups were compared for differences in ratings using Cochran-Mantel-Haenszel tests for ordinal data.

Eight patients were treated with both CEDETA and local anesthetic at different appointments. Responses to both methods of treatment for these eight patients are compared in Tables XII - XXI. The group of eight patients receiving CEDETA and local anesthetic at different appointment times had a patient mean pre-operative apprehension level rating of 0.25, and an operator mean rating of 0.13 for the CEDETA method, as compared with a patient mean rating of 0.38, and an operator mean rating of 0.25 for the local anesthetic method. The CEDETA and local anesthetic methods did not have significantly different patient-rated ($p = 0.782$) or operator-rated ($p = 0.655$) pre-operative apprehension levels (Table XII and Table XIII).

The next assessment of patient discomfort was done after CEDETA was at maximum output or after the injection of local anesthetic. The mean rating of the eight patients was 1.50 with an operator mean rating of 0.63 for CEDETA, as compared with a patient mean rating of 1.75, and an operator mean rating of 1.38 for local anesthetic. The CEDETA and local anesthetic methods did not have significantly different patient-rated ($p = 0.715$) or operator-rated ($p = 0.180$) pain at maximum output or after injection (Table XIV and Table XV).

The third assessment involved the use of the highspeed handpiece by the tooth. The eight patients receiving both types of anesthesia had a mean rating of 1.00 with an operator mean rating of 0.25 for CEDETA, as compared with a patient mean rating of 1.13, and an operator mean rating of 0.50 for local anesthetic. The CEDETA and local anesthetic methods did not have significantly different patient-rated ($p = 0.835$) or operator-rated ($p = 0.317$) pain when the handpiece was by the tooth (Table XVI and Table XVII).

At the completion of the preparation, the group of eight patients receiving both types of anesthesia had a patient mean discomfort level rating of 1.75, with an operator mean rating of

1.50 for CEDETA, as compared with a patient mean rating of 2.63, and an operator mean rating of 1.75 for local anesthetic. The CEDETA and local anesthetic methods did not have significantly different patient-rated ($p = 0.274$) or operator-rated ($p = 0.527$) pain at completion of the preparation (Table XVIII and Table XIX).

The eight patients rated their overall experience at the end of each procedure. The CEDETA patient mean rating was 1.00 with an operator mean rating of 1.25, compared with a patient mean rating of 1.63 and an operator mean rating of 1.50 for local anesthetic. The CEDETA and local anesthetic methods did not have significantly different patient-rated ($p = 0.456$) or operator-rated ($p = 0.564$) overall experience (Table XX and Table XXI).

From the data collected, it was determined that observations made on each patient could be analyzed as independent observations. The ratings of these eight patients did not differ significantly from the ratings of the entire group.

Tables XXII - XXXI compare the entire CEDETA and entire local anesthetic groups for differences in patient and operator ratings between the two methods of treatment. The CEDETA group had a patient mean pre-operative apprehension level rating of 0.28 with an operator mean rating of 0.16, compared with a patient mean rating of 0.23 and an operator mean rating of 0.19 for local anesthetic. The CEDETA and local anesthetic groups did not have significantly different patient-rated ($p = 0.734$) or operator-rated ($p = 0.764$) pre-operative apprehension levels (Table XXII and Table XXIII).

The next assessment of patient comfort was done after the CEDETA device was at maximum output or after injection of local anesthetic. The CEDETA group patient mean rating was 1.34 with an operator mean rating of 0.84, compared with a patient mean rating of 1.94 and an operator mean rating of 1.55 for the local anesthetic group. The CEDETA and local anesthetic

groups did not have significantly different patient-rated ($p = 0.129$) pain at maximum output after injection. However, the CEDETA group did have significantly lower operator-rated ($p = 0.017$) pain at maximum output (Table XXIV and Table XXV).

The third assessment involved the highspeed handpiece by the tooth. The CEDETA group patient mean rating was 1.09 with an operator mean rating of 0.47, versus the local anesthetic group patient mean rating of 0.97 and operator mean rating of 0.55. The CEDETA and local anesthetic groups did not have significantly different patient-rated ($p = 0.664$) or operator-rated ($p = 0.685$) pain when the handpiece was by the tooth (Table XXVI and Table XXVII).

At the completion of the preparation, both groups rated their levels of discomfort. The CEDETA group patient mean rating was 2.16 with an operator mean rating of 1.78, while the local anesthetic group mean rating was 2.29 with an operator mean rating of 1.84. The CEDETA and local anesthetic groups did not have significantly different patient-rated ($p = 0.712$) or operator-rated ($p = 0.822$) pain at the completion of the preparation (Table XXVIII and Table XXIX).

The overall experience of patients in each group were rated at the end of each procedure. The CEDETA group patient mean rating was 1.47 with an operator mean rating of 1.59, versus the local anesthetic group patient mean rating of 1.84 and operator mean rating of 1.55. The CEDETA and local anesthetic groups did not have significantly different patient-rated ($p = 0.346$) or operator-rated ($p = 0.849$) overall experience (Table XXX and Table XXXI). Out of the 63 procedures performed, only one procedure using the CEDETA device required adjunctive anesthesia as did one procedure using local anesthetic.

TABLES

TABLE I

Age distribution of patients

Age	Number	Percent
6 - 7 yrs. 11 mos.	30	47.6%
8 - 9 yrs. 11 mos.	28	44.4%
10 - 11 yrs. 11 mos.	5	8.0%
Total	63	100.0%

TABLE II

Distribution of patients receiving both CEDETA and local anesthetic

Gender	Number	Percent
Male	5	62.5%
Female	3	37.5%
Total	8	100.0%

TABLE III

Distribution of CEDETA and local anesthetic procedures with respect to gender

Gender/anesthetic group	Number	Percent
Male/CEDETA	20	31.7%
Male/Local anesthetic	18	28.6%
Female/CEDETA	12	19.1%
Female/Local anesthetic	13	20.6%
Total	63	100.0%

TABLE IV

Distribution of teeth treated

Tooth	Number	Percent
Upper right 2nd primary molar	10	15.9%
Upper right 1st primary molar	16	25.4%
Upper left 1st primary molar	23	36.5%
Upper left 2nd primary molar	14	22.2%
Total	63	100.0%

TABLE V

Distribution and type of pulp therapy performed

Type of pulp therapy	Number	Percent
No pulp therapy	21	33.4%
Indirect pulp therapy	35	55.5%
Pulpotomy	7	11.1%
Total	63	100.0%

TABLE VI

Comparison of operator-rated and patient-rated pre-operative apprehension levels

		Operator rating					
		0	1	2	3	4	5
Patient rating	0	51	1	1	0	0	0
	1	3	2	0	0	0	0
	2	1	2	1	0	0	0
	3	0	0	1	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0

TABLE VII

Comparison of operator-rated and patient-rated pain after injection of local anesthetic or CEDETA at maximum output

		Operator rating					
		0	1	2	3	4	5
Patient rating	0	15	0	0	0	0	0
	1	4	18	1	0	0	0
	2	1	5	5	0	0	0
	3	0	1	3	0	0	0
	4	0	0	0	3	1	0
	5	0	0	1	3	1	1

TABLE VIII

Comparison of operator-rated and patient-rated pain with highspeed handpiece by the tooth

		Operator rating					
		0	1	2	3	4	5
Patient rating	0	23	1	1	0	0	0
	1	10	9	1	0	0	0
	2	4	6	3	0	0	0
	3	2	1	0	0	0	0
	4	0	0	0	0	0	0
	5	0	1	0	0	1	0

TABLE IX

Comparison of operator-rated and patient-rated pain at completion of preparation

		Operator rating					
		0	1	2	3	4	5
Patient rating	0	3	2	1	0	0	0
	1	0	15	1	1	0	0
	2	0	6	9	1	0	0
	3	0	0	10	0	0	0
	4	0	0	3	5	1	0
	5	0	0	1	2	0	2

TABLE X

Comparison of operator-rated and patient-rated overall experience

		Operator rating					
		0	1	2	3	4	5
Patient rating	0	3	13	2	0	0	0
	1	0	14	1	0	0	0
	2	0	6	10	0	0	0
	3	0	1	4	0	0	0
	4	0	0	0	2	1	0
	5	0	0	0	3	3	0

TABLE XI

Operator and patient rating agreement

	Kappa	Weighted kappa
Pre-operative apprehension level	.443 Moderate	.638 Substantial
After injection of local anesthetic or CEDETA at maximum output	.512 Moderate	.675 Substantial
Highspeed handpiece by tooth	.313 Fair	.438 Moderate
Completion of the preparation	.319 Fair	.521 Moderate
Overall experience	.288 Fair	.743 Substantial

TABLE XII

Patient pre-operative apprehension rating
for patients receiving CEDETA and local anesthetic
at different appointments

	0	1	2	3	4	5	Total
CEDETA	7	0	1	0	0	0	8
Local anesthetic	7	0	0	1	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.782
CEDETA	0.25	0.71	0.25	0.00	2.00	8	
Local anesthetic	0.38	1.06	0.37	0.00	3.00	8	

TABLE XIII

Operator assessment of patient pre-operative apprehension level for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	7	1	0	0	0	0	8
Local anesthetic	7	0	1	0	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.655
CEDETA	0.13	0.35	0.12	0.00	1.00	8	
Local anesthetic	0.25	0.71	0.25	0.00	2.00	8	

TABLE XIV

Patient discomfort rating with CEDETA at maximum output or after injection of local anesthetic for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	0	5	2	1	0	0	8
Local anesthetic	2	3	1	0	1	1	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.715
CEDETA	1.50	0.76	0.27	1.00	3.00	8	
Local anesthetic	1.75	1.83	0.65	0.00	5.00	8	

TABLE XV

Operator assessment of patient discomfort with CEDETA at maximum output or after injection of local anesthetic for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	4	3	1	0	0	0	8
Local anesthetic	2	3	1	2	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.180
CEDETA	0.63	0.74	0.26	0.00	2.00	8	
Local anesthetic	1.38	1.19	0.42	0.00	3.00	8	

TABLE XVI

Patient discomfort rating with highspeed handpiece by the tooth for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	2	4	2	0	0	0	8
Local anesthetic	4	1	1	2	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.835
CEDETA	1.00	0.76	0.27	0.00	2.00	8	
Local anesthetic	1.13	1.36	0.48	0.00	3.00	8	

TABLE XVII

Operator assessment of patient discomfort with highspeed handpiece by the tooth for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	6	2	0	0	0	0	8
Local anesthetic	5	2	1	0	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.317
CEDETA	0.25	0.46	0.16	0.00	1.00	8	
Local anesthetic	0.50	0.76	0.27	0.00	2.00	8	

TABLE XVIII

Patient discomfort rating at completion of the preparation for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	1	3	2	1	1	0	8
Local anesthetic	1	2	0	2	2	1	8

	Mean	*s*	SE	Min	Max	n	p = 0.274
CEDETA	1.75	1.28	0.45	0.00	4.00	8	
Local anesthetic	2.63	1.77	0.63	0.00	5.00	8	

TABLE XIX

Operator assessment of patient discomfort at completion of the preparation for patients receiving CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	0	5	2	1	0	0	8
Local anesthetic	0	3	4	1	0	0	8

	Mean	*s*	*SE*	Min	Max	n	p = 0.527
CEDETA	1.50	0.76	0.27	1.00	3.00	8	
Local anesthetic	1.75	0.71	0.25	1.00	3.00	8	

TABLE XX

Patient rating of overall experience for patients receiving both CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	3	4	0	0	1	0	8
Local anesthetic	3	1	1	2	1	0	8

	Mean	*s*	SE	Min	Max	n	p = 0.456
CEDETA	1.00	1.31	0.46	0.00	4.00	8	
Local anesthetic	1.63	1.60	0.57	0.00	4.00	8	

TABLE XXI

Operator assessment of patient overall experience for patients receiving both CEDETA and local anesthetic at different appointments

	0	1	2	3	4	5	Total
CEDETA	0	7	0	1	0	0	8
Local anesthetic	1	3	3	1	0	0	8

	Mean	s	*SE*	Min	Max	n	p = 0.564
CEDETA	1.25	0.71	0.25	1.00	3.00	8	
Local anesthetic	1.50	0.93	0.33	0.00	3.00	8	

TABLE XXII

Patient pre-operative apprehension rating

	0	1	2	3	4	5	Total
CEDETA	26	3	3	0	0	0	32
Local anesthetic	27	2	1	1	0	0	31

	Mean	*s*	*SE*	Min	Max	p = 0.734
CEDETA	0.28	0.63	0.11	0.00	2.00	
Local anesthetic	0.23	0.67	0.12	0.00	3.00	

TABLE XXIII

Operator assessment of patient
pre-operative apprehension level

	0	1	2	3	4	5	Total
CEDETA	27	5	0	0	0	0	32
Local anesthetic	28	0	3	0	0	0	31

	Mean	s	SE	Min	Max	p = 0.764
CEDETA	0.16	0.37	0.07	0.00	1.00	
Local anesthetic	0.19	0.60	0.11	0.00	2.00	

TABLE XXIV

Patient discomfort rating after injection of
local anesthetic or CEDETA at maximum output

	0	1	2	3	4	5	Total
CEDETA	5	16	7	3	1	0	32
Local anesthetic	10	7	4	1	3	6	31

	Mean	*s*	*SE*	Min	Max	p = 0.129
CEDETA	1.34	0.97	0.17	0.00	4.00	
Local anesthetic	1.94	1.95	0.35	0.00	5.00	

TABLE XXV

Operator assessment of patient discomfort after injection of local anesthetic or CEDETA at maximum output

	0	1	2	3	4	5	Total
CEDETA	10	18	3	1	0	0	32
Local anesthetic	10	6	7	5	2	1	31

	Mean	*s*	*SE*	Min	Max	p = 0.017
CEDETA	0.84	0.72	0.13	0.00	3.00	
Local anesthetic	1.55	1.43	0.26	0.00	5.00	

TABLE XXVI

Patient discomfort rating with highspeed handpiece by the tooth

	0	1	2	3	4	5	Total
CEDETA	11	10	10	0	0	1	32
Local anesthetic	14	10	3	3	0	1	31

	Mean	*s*	*SE*	Min	Max	p = 0.664
CEDETA	1.09	1.09	0.19	0.00	5.00	
Local anesthetic	0.97	1.22	0.22	0.00	5.00	

TABLE XXVII

Operator assessment of patient discomfort with highspeed handpiece by the tooth

	0	1	2	3	4	5	Total
CEDETA	20	11	0	0	1	0	32
Local anesthetic	19	7	5	0	0	0	31

	Mean	*s*	*SE*	Min	Max	p = 0.685
CEDETA	0.47	0.80	0.14	0.00	4.00	
Local anesthetic	0.55	0.77	0.14	0.00	2.00	

TABLE XXVIII

Patient discomfort rating at completion of the preparation

	0	1	2	3	4	5	Total
CEDETA	3	8	10	5	4	2	32
Local anesthetic	3	9	6	5	5	3	31

	Mean	*s*	*SE*	Min	Max	p = 0.712
CEDETA	2.16	1.37	0.24	0.00	5.00	
Local anesthetic	2.29	1.53	0.28	0.00	5.00	

TABLE XXIX

Operator assessment of patient discomfort at completion of the preparation

	0	1	2	3	4	5	Total
CEDETA	1	14	11	4	1	1	32
Local anesthetic	2	9	14	5	0	1	31

	Mean	*s*	*SE*	Min	Max	p = 0.882
CEDETA	1.78	1.04	0.18	0.00	5.00	
Local anesthetic	1.84	1.00	0.18	0.00	5.00	

TABLE XXX

Patient rating of overall experience

	0	1	2	3	4	5	Total
CEDETA	11	9	6	1	2	3	32
Local anesthetic	7	6	10	4	1	3	31

	Mean	*s*	*SE*	Min	Max	p = 0.346
CEDETA	1.47	1.61	0.28	0.00	5.00	
Local anesthetic	1.84	1.51	0.27	0.00	5.00	

TABLE XXXI

Operator assessment of patient overall experience

	0	1	2	3	4	5	Total
CEDETA	2	17	8	2	3	0	32
Local anesthetic	1	17	9	3	1	0	31

	Mean	*s*	*SE*	Min	Max	p = 0.849
CEDETA	1.59	1.04	0.18	0.00	4.00	
Local anesthetic	1.55	0.85	0.15	0.00	4.00	

DISCUSSION

The use of electronic dental anesthesia (EDA) in dentistry offers many potential benefits to patients. Patient fear and apprehension towards dental treatment can be greatly reduced by limiting the need for injections of local anesthetic. Because EDA is non-invasive and requires no needles, pain from injection is eliminated. The risk of needle breakage and paresthesia caused by lacerations of regional nerve fibers is also eliminated when using EDA.

Electronic dental anesthesia reduces the risk of allergic reaction, overdose, and drug interaction problems associated with local anesthetic. Post-operative anesthesia is eliminated, thus reducing the potential lip, cheek and tongue biting that may occur after treatment with local anesthetic. Electronic dental anesthesia is useful for operative procedures on hemophilic patients who otherwise need infusions to prevent hemorrhage from an injection of local anesthetic.

The mode of transmitting impulse signals to the patient varies with different EDA devices. Many earlier devices used extraoral electrodes only. These devices are similar to the electroanalgesic devices used in medicine to treat chronic pain. More recently, EDA devices have been modified to transmit impulses through extraoral and intraoral electrodes, allowing the signals to be directed closer to the targeted area.

In this study, a new type of EDA, Cell Demodulated Electronic Targeted Anesthesia (CEDETA) was compared with local anesthetic. Invasive operative procedures such as the placement of stainless steel crowns and pulp therapy were done rather than Class I and Class II restorations, because simple operative procedures can be done painlessly with no anesthesia at

all. Only primary maxillary molars were involved in the study to limit the variability produced by comparing teeth in the permanent dentition and teeth in different arches.

At five different times during each procedure, patient apprehension and comfort level were evaluated using a 6-point visual analog scale (VAS) (Appendix B). As Cho et al.[93] suggests, a problem common to all visual analogue scales is the limitation imposed by extremes. If a patient rates pain at the worst end of the scale, and then the pain worsens, the measurement stays the same.[93] This is a concern in the present study, because a number of patients did have pain ratings of 5 out of a possible 5 during treatment. Two of these patients did require adjunctive local anesthetic to complete treatment. One of these patients in the CEDETA group gave a pre-operative apprehension level rating of 5 when the highspeed handpiece was held running above the tooth to be treated. Perhaps this patient's anxiety affected her perception of pain and resulted in high discomfort ratings during treatment.

Although no significant differences existed in patient pre-treatment anxiety ratings between the CEDETA and local anesthetic groups, it has been reported by Cho et al.[93] that a relation did exist between reported pain scores during cavity preparation and pre-treatment dental anxiety in 6- to 12-year-old children. Quarnstrom and Milgrom[80] and Hochman[68] had similar findings in adult patients. Cho et al.[93] suggests that measuring pre-treatment anxiety in children could be helpful as a screening process to evaluate their possible acceptance of EDA.

In this study, the discomfort ratings of the 32 patients receiving CEDETA were compared with the discomfort ratings of the 31 patients receiving local anesthetic for dental treatment. Of these patients, eight were treated at two separate visits with random use of CEDETA or local anesthetic. Each of these eight patients was able to serve as his or her own control and thus reduced response variability. At each of the five evaluation steps for these

eight patients, it was found that no significant differences existed in patient ratings between the CEDETA and local anesthetic methods. Operator ratings of patient discomfort also did not vary significantly between the two methods of treatment. These results suggest that the group of eight patients found treatment with CEDETA to be just as effective in controlling pain as treatment with local anesthetic.

Because of the small sample size of the group receiving both CEDETA and local anesthetic, conclusions drawn from comparisons between the two methods could be invalid. Only one patient received local anesthetic first, so that the analysis cannot distinguish between differences in method and differences in the order in which the methods were used.

As with the group of eight patients, for each of the five evaluation steps, the CEDETA group did not have significantly different discomfort ratings compared with the ratings of the local anesthetic group. From the results it can be seen that CEDETA patients were no more apprehensive about dental treatment than local anesthetic patients, and that CEDETA patients found the device no more uncomfortable than an injection of local anesthetic was to local anesthetic patients.

As shown from the patient discomfort ratings at completion of the preparation and for overall experience, the group of CEDETA patients found treatment with the CEDETA device to be as effective in controlling operative pain as patients in the local anesthetic group found local anesthetic. This is a notable finding, because local anesthetic is considered the standard to which all other forms of dental anesthesia are compared.

At each of the five evaluation steps, the operator also rated patient discomfort levels. No significant differences existed in operator ratings between the two groups for patient pre-operative apprehension level, discomfort level with the highspeed handpiece by the tooth,

discomfort level after the preparation, and overall experience. However, operator ratings of patient discomfort with the CEDETA device at maximum output were significantly lower than operator ratings of patient discomfort after injection of local anesthetic. Perhaps the operator had a bias that the tingling sensation of CEDETA at maximum output was less painful to patients than an injection of local anesthetic.

The agreement between the patients' and operator's ratings were measured using Kappa and weighted Kappa statistics. Patient and operator agreement measured by Kappa was fair and moderate, while weighted Kappa showed moderate and substantial agreement of the five ratings (Table XI). In general, the disagreements were due to the patients' rating the pain higher than the operator did. This was most likely, because the patients experienced more discomfort than was expressed to the operator.

While the effects of other EDA devices rely on the principles of Melzack and Wall's gate-control theory of pain, the manufacturer of CEDETA claims that the device works in a way that is significantly different from that of other EDA devices. CEDETA Dental International, while unable to disclose the specific frequencies used in the device due to patent concerns, proposes that the device's technology is physiologically similar to that of local chemical anesthesia.

As per the CEDETA MK2 Operating Manual,[94] the CEDETA device only affects non-myelinated pain (C) fibers and not sensory fibers, which are surrounded by a myelinated sheath. It is interesting to note, however, that tooth pulp is richly innervated with C-fibers and A-delta fibers.[36] C-fibers are small diameter unmyelinated nerves associated with slow, diffuse, long-duration pain, and A-delta fibers are small-diameter myelinated nerves associated with fast, well-defined pain. If the CEDETA device only stops pain impulses from the unmyelinated

C-fibers, it is left unexplained as to how pain impulses from the myelinated A-delta fibers are blocked. Perhaps the CEDETA device stops the A-delta fiber conduction at the nodes of Ranvier, or perhaps CEDETA's pain-controlling effects are based upon the gate-control theory as are other EDA devices. As with other EDA devices, the stimulation of endorphins and serotonin by CEDETA could also contribute to its pain-controlling effects.

Operation of the CEDETA device was fairly simple. Explanations of the device to patients took only a few minutes, and for the most part, patients were very accepting of using the device. For many patients, the device was a distraction during treatment.

On average, 10 minutes were required for patients using the CEDETA device to attain anesthesia adequate for treatment. For many of the patients, this was achieved with the CEDETA device at maximum output. In certain instances, CEDETA's anesthetic effects could have been greater if increased output was available.

In this study, for the procedures performed using CEDETA, output of the device in most cases was at or near the maximum for patients to attain treatment levels of anesthesia. Treatment times averaged 30 minutes. For each CEDETA procedure, four new AA alkaline batteries were used in the device. However, due to the high energy consumption of the device, many times the batteries would weaken 15 to 20 minutes into the procedure and result in a drop of output and decreased patient anesthesia. This would interrupt treatment for the replacement of batteries. Alternate energy sources for the CEDETA device are needed to alleviate this problem.

As with other EDA devices, CEDETA's intraoral electrode is a potential weak link. The intraoral electrode was available in one size only and needed to be trimmed for proper fit. Placement of the electrode was technique-sensitive in that for proper adhesion, it was

imperative that the gingiva be absolutely dry. Although no receptors had come off during treatment, concern existed that over time, saliva could loosen the adhesion of the receptor under the rubber dam resulting in a loss of anesthesia. Also, touching the intraoral electrode with the tongue during treatment could cause a dispersion of the signal and an unpleasant stimulation to the tongue.

CEDETA's effectiveness in providing adequate anesthesia is dependent upon proper patient cooperation. For effective anesthesia, output of the device must be at such a level as to provide a strong sustained stimulation to the patient. If, because of apprehension or a dislike of the tingling sensation, the patient does not have the output at a high enough level, then the anesthesia could be inadequate. This is not a factor when using local anesthetic during dental treatment. Once local anesthetic is given, patients do not have to actively participate in controlling their operative pain.

Because this was not a blind study, the operator could have been more confident with the pain-controlling effects of local anesthetic on account of its track record as a reliable form of anesthesia. When using the CEDETA device, there was always concern that the intraoral receptor would dislodge, or that the device was not set at a sufficient output level to provide the patient with adequate stimulation, or that the batteries would weaken during the procedure and weaken the output.

Although the CEDETA device has shown very promising results in providing pain control during invasive operative procedures, at this time, CEDETA is not a replacement for local anesthetic. Improvements to the CEDETA device are needed as far as alternate power sources, including the ability to run on alternating current. CEDETA also needs more adhesive intraoral receptors and receptors of various sizes. More studies are needed in the future to

evaluate this form of anesthesia. Studies that involve other types of procedures and other teeth, as well as studies with larger patient sample sizes are recommended. Future studies should examine CEDETA's effectiveness when combined with nitrous oxide analgesia.

SUMMARY AND CONCLUSIONS

In this study, the pain-controlling effects of an electronic dental anesthesia device (CEDETA) were compared with those of local anesthetic. Procedures performed were full coverage stainless steel crowns on maxillary primary molars, some of which required indirect pulp therapy and pulpotomies.

At five different times during each procedure, the patient and operator rated the patients' perception of pain using a 6-point visual analog scale. There were 32 procedures performed using the CEDETA device, and 31 using local anesthetic. A total of 55 children aged 6 years, 0 months, to 10 years, 6 months participated in this study. Of these 55 children, eight were treated with both CEDETA and local anesthetic at different appointments and thus acted as their own controls.

For each of the five evaluation steps, significant differences in discomfort ratings did not exist between the CEDETA and local anesthetic methods for the group of eight patients and for the entire group. Operator ratings of patient discomfort did not vary significantly between the two methods of anesthesia for each of the evaluation steps except at maximum output or after injection, where the CEDETA group had significantly lower operator-rated pain. In general, patients tended to rate their perceptions of pain higher than those of the operator. Most likely the patients experienced more discomfort than was expressed to the operator.

It is noteworthy that the operator and patients in this study found CEDETA to be as effective as local anesthesia for controlling dental operative pain; however, a number of

negative factors involved in the use of the CEDETA device must be taken into consideration. A substantial monetary investment is required to purchase the CEDETA system as well as the necessary disposable electrodes. Although no receptors became loose in this study, the adhesive ability of the intraoral electrode over time is a potential weak link.

AA alkaline batteries must also be purchased for the CEDETA device to operate. During treatment conducted in this study, the CEDETA device rapidly consumed batteries. Many times two sets of AA alkaline batteries were required for each procedure. Energy source improvements to the CEDETA system are needed.

Time also must be devoted to allow the operator to learn how to use the CEDETA device and to train auxiliary staff with its usage. Set-up and break-down times for procedures are also increased when using this form of anesthesia compared with local anesthesia. Additional time must be spent introducing the CEDETA device to patients and educating them with its usage. These factors all contribute to increased expense and inconvenience when using CEDETA. A significant increased fee to the patient could help to justify the increased operating expense involved when using CEDETA for dental operative procedures.

Results from this study are very promising and show that the CEDETA system can be effective in controlling dental operative pain. However, CEDETA is not a practical replacement for local anesthetic, especially in a busy pediatric dental practice.

More studies are needed to evaluate this new system, especially if improvements are made to the device, its power source, and to the intraoral receptor. Also, it would be useful to examine the effectiveness of CEDETA combined with nitrous oxide analgesia. Additionally,

investigations involving different teeth and different procedures as well as studies with larger sample sizes would be beneficial in evaluating this form of anesthesia.

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APPENDIXES

APPENDIX A

Study No: 9506-22

IUPUI INFORMED CONSENT STATEMENT

for

THE USE OF CELL DEMODULATED ELECTRONIC TARGETED ANESTHESIA TO CONTROL DENTAL OPERATIVE PAIN IN PEDIATRIC PATIENTS

You are invited to participate in a research study, entitled The Use of Cell Demodulated Electronic Targeted Anesthesia to Control Dental Operative Pain in Pediatric Patients.
The purpose of this study is to compare the pain control effects and patient preference of Electronic Dental Anesthesia (CEDETA) versus local chemical anesthetics (novocaine) administered by injection prior to restoring teeth. If you agree to participate, you will be one of approximately 60 subjects who will be participating in this research.

We are asking you and your child to participate because your child needs a dental appointment which would typically require the use of medicine to numb the teeth. At this appointment, your child will receive either local chemical anesthetic used in our clinic or receive the patient controlled electronic anesthetic device, CEDETA, to produce the pain control necessary to restore the decayed tooth. The method to be used on your child will be determined by the flip of a coin, it will be determined completely by chance. At the appointment, your child will be asked to rate his/her discomfort before, during, and after the procedure is completed.

There are no known risks associated with CEDETA. However, some discomfort associated with the procedure may occur with the chemical numbing medicine or CEDETA. Should the initial numbing medicine used not be enough for pain control, additional numbing medicine will be given. It is possible that the CEDETA device will be ineffective in providing pain control. Should the anesthesia be ineffective from the CEDETA device, your child will be given the chemical numbing medicine. Patients who have the following conditions will be excluded from the study: cardiac pacemaker, cochlear implant, history of epilepsy, taking drugs Prozac or Elavil.

When CEDETA is used, two control pads will be placed on the back of each hand and a receptor will be attached to an area of gum tissue inside your child's mouth. A small electric current derived from four AA batteries will be established. A slight "tingling" sensation will be felt in the area of the receptor during the procedure. The patient will control how strong the current is during treatment with guidance from the investigator. After the completion of treatment, the current will be turned off, and the pads and receptor will be removed.

During the procedure when the dentist is removing the area of decay with the dental handpiece, your child will be asked to assess the level of discomfort felt. He/she will be asked to report the sensation felt immediately following each step of the preparation.

While the incidence of adverse reactions to any local chemical anesthetic is small, potential risks do exist. They can be broken down into those affecting the whole body and local complications. Complications that affect the whole body involve toxicity, allergies and overdose. The risks associated with these complications include nervousness, dizziness, blurred vision, tremors, drowsiness, convulsions, unconsciousness and even life threatening reactions such as respiratory arrest. Local complications include bruising, swelling, muscle pain, prolonged numbness, pain on injection, needle breakage, and lip or tongue chewing. These systemic and local risks will be minimized by strictly adhering to injection techniques, maximal dose calculations of local chemical anesthetics, attention to the patient's past medical history, close observance of the patient, and appropriate postoperative instructions to the patient or legal guardian.

_____
Subject's Initials
(ICS.08/95)

(APPENDIX A - CONTINUED)

In the unlikely event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. You should understand also that it is your responsibility to determine the extent of your health care coverage.

If you and your child agree to participate in this study, please read the statement below and sign where appropriate.

We have been given an opportunity to ask questions about this study; answers to such questions (if any) have been satisfactory. The specific information in the study will be kept confidential and will be made available only to the person conducting the study unless we specifically give permission, we will not be identified. We understand that the results of the study may be submitted to the Food and Drug Administration.

If I have any questions regarding the study, I can reach Dr. David Avery or Dr. Gary Toppi at 317-274-3865 between 8:00 a.m. - 5:00 p.m. Monday - Friday. If I am unable to reach Dr. Avery or Dr. Toppi at this number in an emergency, I may call 317-274-5000 and ask for the pediatric dentistry resident on call.

The dental procedures for using CEDETA have been explained to me by Dr. Gary Toppi and/or his associates.

A patient representative who is not associated with this research to whom you may address complaints about this study, as well as questions about your rights as a research participant, may be reached at 317-274-6637 at Riley Hospital.

My child's participation in this research may be terminated without my consent if he/she refuses to accept local chemical anesthesia or CEDETA for the restoration or by refusing to answer the questions asked about the procedures.

In consideration of all of the above, I give my consent to participate in this research study. I understand that I may drop out of or be withdrawn from the study without fear of changing the investigator's interest or the quality of medical care which I may seek or receive in the future from the doctors participating in the study.

I acknowledge receipt of a copy of this informed consent statement.

SUBJECT'S SIGNATURE_____DATE:_____ _____

(IF SUBJECT IS A MINOR:) SIGNATURE OF PARENT_____

SIGNATURE OF PARENT_____

(AGE 7 AND ABOVE:) SIGNATURE OF CHILD_____

SIGNATURE OF WITNESS

_____

(May be investigator or person obtaining consent.)

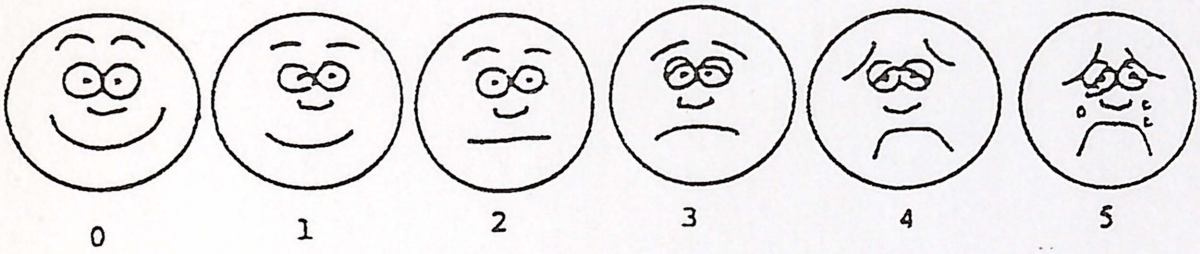
(ICS.08/95)

APPENDIX B

Six Point Visual Analog Scale (VAS)[97]

The children are asked to assess their level of comfort or distress by selecting the most appropriate facial type at various times during two separate dental appointments. It will be explained to the patient that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain. Face O is very happy because he doesn't hurt at all. Face 1 hurts just a little bit. Face 2 hurts a little more. Face 3 hurts even more. Face 4 hurts a whole lot. Face 5 hurts as much as you can imagine, although you don't have to be crying to feel this bad. Once this has been carefully explained in the same manner to each patient, they will be asked to choose the face that best describes the way they are feeling at the aforementioned times during the two dental appointments. Their facial type selections will be quantitatively recorded as follows:

0	1	2	3	4	5
NO PAIN	LITTLE	MEDIUM	QUITE A LOT	VERY BAD	WORST PAIN



When using the Faces, it is explained to the person that each face is for a person who feels happy because he has no pain (hurt for young children) or sad because he has some or a lot of pain. Face 0 is very happy because he doesn't hurt at all. Face 1 hurts just a little bit. Face 2 hurts a little more. Face 3 hurts even more. Face 4 hurts a whole lot. Face 5 hurts as much as you can imagine, although you don't have to be crying to feel this bad. It is important to emphasize this, as well as the patient can be crying at some of the other levels of pain. When you are sure the patient understands the directions, ask the person to choose the face that best describes how he or she is feeling.

APPENDIX C

LOCAL ANESTHETIC APPOINTMENT

PATIENT'S NAME _____

AGE _____

SEX _____

DATE _____

PATIENT # _____

TOOTH #_____

TYPE OF PULP THERAPY, IF ANY_____

TYPE OF RESTORATION_____

PATIENT RATING (0-5)

1) Pre-Op Apprehension Level _____

2) After injection of Local Anesthesia. _____

3) Highspeed Handpiece by the Tooth _____

4) Completion of the Preparation _____

5) Overall Experience _____

APPENDIX D

CEDETA APPOINTMENT

PATIENT'S NAME _____

AGE _____

SEX _____

DATE _____

PATIENT # _____

TOOTH #_____

TYPE OF PULP THERAPY, IF ANY_____

TYPE OF RESTORATION_____

PATIENT RATING (0-5)

1) Pre-Op Apprehension Level _____

2) CEDETA at Maximum Voltage _____

3) Highspeed Handpiece by the Tooth _____

4) Completion of the Preparation _____

5) Overall Experience _____

APPENDIX E

OPERATOR ASSESSMENT

PATIENT'S NAME _____

AGE _____

SEX _____

DATE _____

PATIENT # _____

CEDETA APPOINTMENT (GROUP A)

TOOTH #_____

TYPE OF PULP THERAPY, IF ANY_____

TYPE OF RESTORATION_____

OPERATOR RATING (0-5)

1) Pre-Op Apprehension Level _____

2) CEDETA at Maximum Voltage _____

3) Highspeed Handpiece by the Tooth _____

4) Completion of the Preparation _____

5) Overall Experience _____

LOCAL ANESTHETIC APPOINTMENT (GROUP B)

TOOTH #_____

TYPE OF PULP THERAPY, IF ANY_____

TYPE OF RESTORATION_____

OPERATOR RATING (0-5)

1) Pre-Op Apprehension Level _____

2) After injection of Local Anesthesia. _____

3) Highspeed Handpiece by the Tooth _____

4) Completion of the Preparation _____

5) Overall Experience _____

ABSTRACT

THE USE OF CELL DEMODULATED ELECTRONIC TARGETED ANESTHESIA TO CONTROL DENTAL OPERATIVE PAIN IN PEDIATRIC PATIENTS

by

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The pain-controlling effects of a recently introduced electronic dental anesthesia device (CEDETA) were compared with those of local anesthesia in this study. Procedures performed involved full-coverage stainless steel crowns on maxillary primary molars, some of which required indirect pulp therapy and pulpotomies.

A total of 55 children, aged 6 years to 10 ½ years, were randomly selected to have treatment done with CEDETA or local anesthetic. Eight of these patients were treated with both CEDETA and local anesthetic at different appointments. At various times during each procedure, the patient and operator rated the patient's level of discomfort using a 6-point Visual Analog Scale.

For each of the five evaluation steps, no significant differences existed in discomfort ratings between the CEDETA and local anesthetic methods for the group of eight patients or for the entire group. Operator ratings of patient discomfort did not vary significantly between the two methods of anesthesia for each of the evaluation steps, except at the step of maximum output or after injection, when the CEDETA group as a whole had significantly lower operator-rated pain. In general, patients tended to rate their perceptions of pain higher than those of the operator.

Although the operator and patients in this study found CEDETA to be as effective as local anesthetic for controlling dental operative pain, a number of factors must be considered when deciding to use this type of electronic dental anesthesia. A substantial monetary investment is required to purchase the CEDETA device and the disposable electrodes and batteries to power the unit. There is an increased operating expense for each procedure done when using CEDETA, because of the additional time needed for the operator, staff, and patients to become familiar with the use of the device. Additional set-up and break-down time is also needed when using CEDETA as opposed to local anesthetic.

CURRICULUM VITAE

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Professional Organizations

California Society of Pediatric Dentists
Children's Dental Health Associates of San Diego
American Academy of Pediatric Dentistry
American Dental Association